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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,090	05/15/2006	Xina Nair	PC23207A	7765
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PFIZER INC. PATENT DEPARTMENT Building 114 M/S 114 EASTERN POINT ROAD GROTON, CT 06340				
EXAMINER				
POCHAS, CHRISTOPHER M				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
08/07/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

-IPGSGro@pfizer.com

Office Action Summary

Application No.

10/544,090

Applicant(s)

NAIR, XINA

Examiner

Christopher Pochas

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Office Action

Receipt is acknowledged of Applicant's amendments and remarks filed 3/6/2009.

Acknowledgment is made of the following:

Independent claim 9 has been amended to include an effective amount of 4-cyclopentyl resorcinol or a pharmaceutically acceptable salt thereof.

New claims 20-22 have been added.

Applicant has argued unexpected results in the form of the data provided in their remarks and specification.

New Rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 9, 20, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu, U.S. Patent 6132740, issued October 17th, 2000, Vonbehren et al., U.S. Patent Application Publication US 2006/0115438 A1, filed September 18th, 2003, and Friedman et al., U.S. Patent Application Publication US 20060269485 A1, which has support in its provisional application 60429546, filed November 29th 2002.

Regarding pending claim 9, U.S. Patent 6132740 (hereafter the 740 patent) discloses the pharmaceutical use of a topical solution consisting of ethanol and propylene glycol in a 7:3 ratio and containing 4-cyclopentyl resorcinol at 5% as the active agent (first paragraph of column 12). The 740 patent does not teach dimethyl isosorbide, nor hexylene glycol, nor the specific amounts of pending claim 9.

U.S. Patent Application US 2006/0115438 A1 (hereafter the 438 document) discloses in its paragraph 55 the use of about 5% to about 75% of one or more penetration enhancers, one of which may be dimethyl isosorbide. Though the 438 document is directed towards a cosmetic composition, it is known in the art to include penetration enhancers in any topical composition, cosmetic or pharmaceutical, where one desires the absorption of some agent. The 438 document does not teach hexylene glycol as a penetration enhancer however it does teach the use of multiple penetration enhancers.

U.S. Patent Application Publication US 20060269485 A1 (hereafter the 485 document) discloses in its claim 28 that hexylene glycol and propylene glycol are

equivalent penetration enhancers. These are taught to be used from 5-10% in the formulations of example 6, located at paragraph 199.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the specific blend of penetration enhancers of pending claim 9 with 4-cyclopentyl resorcinol. One would have been motivated to do so because propylene glycol and ethanol have been used with 4-cyclopentyl resorcinol in the art and as for the others, paragraph 55 of the 438 document teaches the inclusion of multiple different penetration enhancers, in an amount from 5% to 75% (paragraph 55) in topical compositions, as well as the manipulation of the amount of penetration enhancers. In light of the disclosure of the 438 document, one would have been motivated to optimize the ranges of penetration enhancers by routine experimentation. As for hexylene glycol, it is taught by the 485 document to be a penetration enhancer equivalent to propylene glycol. Furthermore, the 438 document teaches a total amount of penetration enhancers which overlaps with the ranges of the pending claims. One would have had a reasonable expectation of success in doing this because all the compounds are known in the art to be penetration enhancers.

Furthermore, section 2144.05 of the MPEP states, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In *re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It further states, "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists. In *re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

Regarding pending claims 20 and 22, the 740 patent teaches a range of 0.1% to 10% for the active agent taught therein, 4-cyclopentyl resorcinol, which obviates the claimed range of "about 1-2%".

Regarding pending claim 21, the limitations of this claim have been discussed *supra*.

Response to Arguments

Applicant has argued unexpected results in the form of the data showing the mean depigmentation values of various compositions which was provided in their response as well as the instant specification. These results are not found persuasive for the reason that they are not unexpected. One of ordinary skill in the art would have expected that the absorption and therefore activity of the composition could be improved by optimizing the content of penetration enhancers, as has been discussed *supra*. Furthermore, the error bars relating to the standard deviations of these data are very large, and as a result the data is inconclusive.

4.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pochas whose telephone number is

(571)270-7722. The examiner can normally be reached on Monday to Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CMP/

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611